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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,327	12/03/2003	John Kirchgeorg	LIFE02WAB	5961

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	
MAIL DATE	DELIVERY MODE
01/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,327	KIRCHGEORG ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11, 14, 16-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold, Jr. (Pat. No. 4,060,079) in view of Hood et al. (Pat. No. 5,975,081).

Regarding claim 11, Reinhold, Jr. discloses a multi-component emergency medical system (see col. 1, lines 4-7) of a size and weight which can easily be carried by a single hand (see col. 2, lines 2-7, col. 7, lines 7-15, etc.) comprising: a breathable oxygen delivery system 76; a defibrillation system (see col. 3, lines 11-20); at least one measurement system (again reference is made to col. 3, lines 11-20); and a unitary casing (oxygen container supporting assembly 16 and/or overall frame structure) for housing said oxygen delivery system, said defibrillation system and said measurement system (see for example col. 7, lines 30-49); the cumulative size and weight of the unitary casing, oxygen delivery system, defibrillation system, and measurement system such that the unitary casing, when housing the oxygen delivery system, defibrillation system and measurement system can easily be carried by a single hand (see col. 2, lines 2-7, col. 7, lines 7-15, etc.).

While Reinhold, Jr. does not elaborate on the use of a measurement system(s) for measuring at least one of blood or gas content, saturation, affinity or perfusion, the crux of the invention is to provide emergency heart-lung resuscitation. Those of ordinary skill in the emergency heart-lung resuscitation arts would have recognized the obviousness of including at least one such monitor in the system of Reinhold, Jr., because it is well-known that knowledge of blood or gas content, oxygen saturation, etc., is vitally important to proper emergency care and early diagnosis of patient

condition. Knowledge of low oxygen saturation, for example, may necessitate emergency CPR and/or defibrillation procedures in order to provide the victim with adequate oxygen supply.

In any event, and independently of the above reasoning, Hood et al. additionally disclose a related emergency medical system that may include a variety of sensors including an oxygen saturation sensor, carbon dioxide sensor, etc. (note for example col. 3, lines 43-52 and col. 5, lines 55-62). It is taught that such equipment is crucial to providing timely and proper emergency treatment during the "golden hour" –the time during which a patient's chances for survival are greatly enhanced if proper treatment can be immediately provided (see col. 1, lines 12-52). Given that both the Reinhold, Jr. and Hood et al. inventions are concerned with emergency medical treatment and have similar functioning, those of ordinary skill in the art desiring to provide immediate treatment in order to enhance the victim's chances for survival, would have seen the obviousness of including this well-known piece of medical diagnostic equipment in the system of Reinhold, Jr..

Regarding claim 14, while Reinhold, Jr. does not elaborate on the specific type of defibrillator system used, the examiner had taken Official Notice in the previous Office Action that AEDs are well-known portable and standard emergency equipment (attention is drawn to the applicants' own patent specification col. 1, lines 20-35). Automatic systems are especially useful in high stress emergency situations where operator error may severely affect the survivability of the patient. Said systems aid the caregiver by relieving the burden and responsibility of decision making, and have

proven reliability and effectiveness in the field. As this Notice was not traversed, the feature is now considered admitted prior art.

Regarding claim 18 and claims with similar limitations, Reinhold Jr. does not discuss the use of a prompting system for directing a user through a protocol employing the oxygen delivery system and at least one measurement system. Hood et al., however, disclose a communications system 817 with microphone and speaker for communicating information and instructions from trained medical personal to the control circuit and local care giver (see for example the text abridging cols. 22 and 23). Hood et al. also teach that the control circuit can be used to train emergency personnel in the operation of the device (see col. 23, lines 42-49). Directing a novice user through a protocol is a standard training tactic to ensure that the user is performing the correct procedure and to ensure that the user has confidence in using the equipment. Such prompting systems are a well-known and desirable technique in the medical arts to aid the rescuer in high stress emergency situations where human error may lead to disastrous consequences (in the same manner that one calling 9-1-1 may get prompts, instructions or assistance from a remote center staffed by personnel with superior medical training). Such systems are commonplace in emergency treatment devices such as the AED. To implement similar techniques to improve related emergency systems in order to provide the most effective treatment and eliminate operator error would have therefore been considered obvious to those of ordinary skill in the art.

Regarding claim 19 (with similar comments applying to claims 20, 24 and 25), while Reinhold Jr. does not discuss the use of a control processor for moderating the

prompting system to direct the user based on feedback from at least one measurement system, the courts have indicated that the automation of a manual activity to accomplish the same result is not sufficient to distinguish over the prior art (see *In re Venner*, 262 F. 2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)). Here the machine is merely replacing the actions of the physician. For example, a physician or paramedic detecting low blood oxygen level would likely initiate oxygen delivery or other appropriate therapy, or in the very least, direct those with access to the treatment system on the proper procedure for doing so. The applicants' in fact state that such protocols for the coordination of oximetry, oxygen delivery, and defibrillation are known in the medical arts (col. 3, lines 54-57). Furthermore, such prompting systems for emergency equipment in general are old and well-known in the art. Hood et al., for example, teaches that a verbal communication system may be employed to regulate operation of the field device to improve effectiveness of treatment. Official Notice was taken in a previous Office Action that AED devices, for example, commonly provide on-screen or voice command instructions (attention is directed to col. 1, lines 20-28, col. 3, lines 44-54 and the text abridging cols. 3 and 4 of the applicants' 497 patent) for proper placement of electrodes, shock procedure, and safety warnings in an effort to lessen the chances for human error in high stress situations. It would be reasonable to expect similar beneficial and predictable results for other emergency equipment often used in locations remote from primary care centers. To include a prompting system to direct an operator on proper use of the oxygen delivery system based on the results of diagnostic measurements

would have therefore been considered a matter of obvious design. As the Official Notice was not traversed, this feature is now considered to be admitted prior art.

Regarding claims 21 and 26, Reinhold Jr. discloses that a wide variety of monitors and therapy devices (e.g., defibrillator) may be incorporated into the system (see for example col. 3, lines 11-21). While the use of a display *per se* is not discussed, those of ordinary skill in the art would have readily understood said monitoring and therapy equipment to include displays as is old and well-known in the medical arts. Hood et al., for example, disclose a related system wherein displays are employed to convey information to the medical technician/user (see for example displays 84, 88, 25, etc.). Clearly the use of a display to convey vital information to caregivers on patient condition is crucial to providing adequate and effective treatment. As such, the inclusion of a display system would have been considered blatantly obvious to those of ordinary skill in the medical treatment arts.

5. Claims 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold Jr. and Hood et al. in view of Dudley (Pat. No. 3,905,363) or Sundblom et al. (Pat. No. 3,820,566).

Reinhold Jr. does not discuss means for controlling the oxygen delivery system, for switching or prompting a user to switch said oxygen delivery system between a variable flow rate/pressure cyclic ventilator mode and a fixed flow rate mode. Dudley teaches the importance of utilizing separate ventilator modes of operation depending on the patient's needs, where one mode intrinsically involves variable flow rates to assist the patient's breathing based on demand and the other mode involves

fixed flow rates without feedback to completely control the intake of fluid when a patient is not breathing (see for example cols. 1 and 2). Since the ability to provide for different modes of operation to account for the patient's condition is a decided advantage and well-known in the art, those of ordinary skill looking to enhance the versatility and thus the effectiveness of treatment, would have considered incorporation of the means for modal control into the system defined by Reinhold Jr. and Hood et al. to be obvious.

Sundblom et al. disclose a versatile, compact ventilator and teach that prior to their invention, users had little, if any, opportunity to adjust flow rates --flow rates were essentially always fixed (see col. 1, lines 26-43). Sundblom et al. also teach in the same section that because it is desirable to have a large initial flow at the beginning of the inspiratory phase with diminished flow towards the end of the phase, the ability to provide variable flow rates is advantageous. As stated in the text abridging columns 2 and 3, flow and pressure can be automatically adjusted or manually set. Given the recognized need to enable various flow/pressure modes depending on the particular situation at hand and given the disclosure that such control affords the user a versatile and effective way to treat the patient, those of ordinary skill in the art would have seen the obviousness of incorporating flow rate/pressure modal control into the system defined by Reinhold Jr. and Hood et al..

Response to Arguments

6. Applicant's arguments concerning the portability of the Andrews et al. invention and the lack of motivation to modify the system to be easily carried by a single hand,

filed October 20, 2008, have been fully considered and are persuasive. The rejection of claims based on this reference has been withdrawn.

Reissue Applications

7. The applicants are reminded that any amendment in response to this rejection must be accompanied by a supplemental oath/declaration.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
January 22, 2008